K123249

Section 5 - 510(k) Summary

FEB 8 2013

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter: Edan Instruments, Inc.

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Contact Person: Randy Jiang

Prepare date: Sep 25, 2012

2. Device name and classification:

Device Name:

Diagnostic Ultrasound System, Model U50

Classification Name:

892.1550 System, Imaging, Pulsed Doppler, Ultrasonic

Product code: IYN

892.1560 Ultrasonic, Pulsed echo, Imaging

Product code: IYO

892.1570 Transducer, Ultrasonic, Diagnostic

Product code: ITX

Regulatory Class: Class II

3. Predicate Device:

DUS 60 Digital Ultrasonic Diagnostic Imaging System / K110999 / Edan Instruments, Inc.

DC-6 Diagnostic Ultrasound System / K072164 / Shenzhen Mindray Bio-medical Electronics Co., Ltd.

M5 Diagnostic Ultrasound System / K102991 / Shenzhen Mindray Bio-medical Electronics Co., Ltd.

GE LOGIQ E9 Diagnostic Ultrasound System/ K082185/ General Electric Co.

4. Device Description:

The U50 is a portable Diagnostic Ultrasound System, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Multi-Beam-Forming (mBeam), Speckle Resistance Imaging (eSRI), and Spatial Compounding Imaging, etc. Various image parameter adjustments, 12.1 inch LCD and diverse probes are configured to provide clear and stable images.

Its function is to acquire and display Ultrasound images in B-mode, M-mode, PW-mode, Color-mode, PDI/DPDI mode. This system provides a series of probes that include linear array, convex array, micro-convex array with a frequency range of approximately 2.5 MHz to 11 MHz.

5. Intended Use:

The diagnostic ultrasound system (U50) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), transvaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

6. Effectiveness and Safety Considerations:

Clinical test:
Clinical testing is not required.

Non-clinical test:
The following safety standards are conducted on the subject device:
(1) IEC 60601-1 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(4) ISO 10993-1, ISO 10993-5 and ISO 10993-10

7.Comparison to the predicate device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety and the same needle-guide bracket material, property, and sterilization methods as the predicate devices.

The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

8. Substantially Equivalent Determination

Verification and validation testing was conducted on the U50 Diagnostic Ultrasonic System.

This premarket notification submission demonstrates that U50 Diagnostic Ultrasonic System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 8, 2013

Edan Instruments, Inc.
c/o Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories
333 Pfingsten Rd.
NORTHBROOK IL 60062

Re: K123249
Trade/Device Name: U50 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 17, 2013
Received: January 30, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the U50 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C352UB	E612UB	C422UB
L1042UB	C612UB	L552UB
L742UB	C6152UB	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: U50 Diagnostic Ultrasound System

Intended Use:

The diagnostic ultrasound system (U50) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), transvaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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(Division Sign Off)
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Office of *In Vitro* Diagnostic and Radiological Health
510(k)_____

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Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123249

Diagnostic Ultrasound Indications for Use Form

U50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	Note 1,2
	Abdominal	N	N	N		N	N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2
	Small Organ (Specify) *	N	N	N		N	N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	Note 1,2
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1,2
	Intravascular							
	Other (Specify) **	N	N	N		N	N	Note 1,2
Cardiac	Adult Cardiac	N	N	N		N	N	Note 1,2
	Pediatric Cardiac	N	N	N		N	N	Note 1,2
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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510(k) K123249

Diagnostic Ultrasound Indications for Use Form

U50 with C352UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	Note 1,2
	Abdominal	N	N	N		N	N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N		N	N	Note 1,2
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with L1042UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N		N	N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with L742UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N		N	N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with E612UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	Note 1,2
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with C612UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac	N	N	N		N	N	Note 1,2
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with C6152UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac	N	N	N		N	N	Note 1,2
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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Diagnostic Ultrasound Indications for Use Form

U50 with C422UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	N	N	N		N	N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac	N	N	N		N	N	Note 1,2
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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510(k) K123249

Diagnostic Ultrasound Indications for Use Form

U50 with L552UB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2
	Small Organ (Specify) *	N	N	N		N	N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

* Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent.

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